

Remarks

Claims 1, 6, 7, and 8 are amended and claims 9-12 are added by this amendment. Claims 1-12 will be pending upon entry of this amendment. Applicant acknowledges with gratitude the allowability of claim 5.

In response to Examiner's comments regarding the title, the title of the invention is herein amended to "Surgical System for Use in the Course of a Knee Replacement Operation" and is believed to be descriptive.

New claim 9 corresponds to claim 5 rewritten in independent form. Claim 5 was objected to only as depending from rejected base and intervening claims and therefore, new claim 9 is believed to be in form for allowance.

I. Response to Objections of Claims

Claim 6 has been amended in accordance with the Examiner's suggestion.

II. General Considerations

This invention relates to a surgical system and apparatus for use in the course of a knee replacement operation. In performing knee replacement operations it is desirable to check the alignment of the knee joint in both flexion and tension before and/or after the tibia has been resected, but before the femur is resected, and make any necessary soft tissue release prior to the surgeon cutting bone, especially the femur in readiness for implantation of the femoral component.

A healthy knee is held together by four ligaments which join the tibia and femur together. These are the anterior and posterior cruciate ligaments and the medial and lateral ligaments. Since the components of the knee implant may intrude on the space normally occupied by the cruciate ligaments these are often sacrificed in the course of implantation of an artificial knee. Hence only the medial and lateral ligaments remain in such a case, one on each side of the knee, to hold the joint together.

In a diseased or damaged knee there is often erosion of bone on the medial side. This has the effect of lowering the knee on that side and causing some bow-leggedness. At this side of the knee the ligament tends to go slack and then tighten up in the course of a step taken by the patient. Another common condition is a fixed flexion deformity in which the knee will not straighten due to the soft tissue joint capsule adhering to the bone. The knee implantation operation is intended to correct any such defects in the patient's knee. Hence an important part of any knee replacement operation is to try to ensure that the length of, and tension in, the patient's medial and lateral ligaments are restored to their natural values. Thus, the claimed surgical system provides a very material advantage in the field of knee replacement operations.

III. Response to Rejections of Claims

A. Claim 1

Claim 1, as amended, is directed to a system for use by a surgeon during implantation in a patient of a tibial implant and of a femoral implant in the course of a knee replacement operation. The system comprises:

a) a computer having memory for holding data relating to size and shape of at least one tibial implant and at least one femoral implant as well as data obtained during pre-operative scanning of the patient relating to the tibia and femur of the patient and also data relating to the three dimensional position and orientation of at least one bone selected from the patient's tibia and the patient's femur obtained during the course of the knee replacement operation;

b) display means for displaying images derived from data held in the memory of the computer relating to the patient's tibia, to the patient's femur, to the at least one tibial implant, and to the at least one femoral implant;

c) registration means for registering the three dimensional position and orientation of the at least one bone during the course of the knee replacement operation;

d) detector means connected to the computer and operatively coupled to the registration means for detecting the position and orientation of the at least one bone and for supplying to the memory of the computer data relating to the three dimensional position and orientation of at least one bone selected from the patient's tibia and the patient's femur obtained during the course of the knee replacement operation; and

e) tensor means for applying tension to the ligaments of the patient's knee in flexion or in extension;

f) the computer being programmed to display on the display means, *inter alia*, one or more of the following images derived from data held in the memory of the computer and depicting the position and orientation of:

(i) the patient's tibia and the patient's femur prior to resection of the femur with the knee tensed by the tensor means in flexion;

(ii) the patient's tibia and the patient's femur prior to resection of the femur with the knee tensed by the tensor means in extension;

(iii) the patient's tibia and the patient's femur prior to resection of the femur with the knee tensed by the tensor means in flexion and potential planes of cut for resection of the patient's femur;

(iv) the patient's tibia and the patient's femur prior to resection of the femur with the knee tensed by the tensor means in extension and potential planes of cut for resection of the patient's femur;

(v) the patient's tibia and the patient's femur prior to resection of the femur with the knee tensed by the tensor means in flexion and with at least one component selected from the tibial component and the femoral component as it will appear after implantation thereof; and

(vi) the patient's tibia and the patient's femur prior to resection of the femur with the knee tensed by the tensor means in extension and with at least one component selected from the

tibial component and the femoral component as it will appear after implantation thereof.

Claim 1 is submitted as patentable over the references of record, including the combination of U.S. Patent No. 6,533,737 (Brosseau et al.) and U.S. Patent No. 5,611,353 (Dance et al.), in that none of them show or suggest a tensor means.

As indicated by the Examiner, Brosseau et al. fail to mention a tensor means and therefore, is not pertinent to the distinction that applicants submit make the present invention patentable.

Dance et al. teach a computer-assisted surgery system having a support arm 34. It is stated at column 4 line 61 that the "support arm 34 is connected to registration clamp 30 and is used to rigidly position femur 10." While there is reference to arm 34 being used to move the patient's leg through full flexion to full extension, there is no reference of the arm being used for applying tension to the ligaments of the knee.

Column 5, line 31 to column 6, line 22 describe the steps illustrated by Figs 5a to 5c. "FIGS. 5a through 5c show the steps used to intraoperatively locate the patient's weight bearing axis using the apparatus of the current invention." While this technique can apparently be used to get the patient's leg aligned correctly, Dance et al. do not recognize the need to get the tensions in the medial and lateral ligaments correct. Even if the implantation of the knee results in the leg being correctly aligned in extension and so that when the leg is in a weight bearing configuration (i.e. effectively straight, after the operation has been completed) the leg will bear the patient's weight, yet nevertheless the patient's lower leg can still flail around when the patient's leg is bent and is not bearing weight, if care is not taken to balance the tension and lengths of the medial and lateral ligaments both in flexion and also in extension.

Dance et al. fail to recognize the importance of checking the medial and lateral ligaments with the leg in both flexion and

extension. As stated at column 5, lines 41 and 42, "Tibia 12 is left to hang from femur 10 by the attaching ligaments." This will result in an uncontrolled tensioning of the ligaments. It will tell the surgeon nothing about how much soft tissue release is necessary to properly align the medial and lateral ligaments.

Moreover, applicant has invoked 35 U.S.C. §112, para. 6 in claiming this invention (i.e., as to the "tensor means"). Accordingly, to determine whether the prior art meets the tensor means requirement, an analysis in accordance with the requirements of 35 U.S.C. §112 must be performed. "[T]he PTO is not exempt from following the statutory mandate of Section 112 Para. 6, which reads:

An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof."

In re Allappat, 31 U.S.P.Q.2d 1545, 1554 (Fed. Cir. 1994).

Several versions of the tensor means are described in the present specification. As stated on page 13, line 30 through page 14, line 8, the tensor means can be an inflatable balloon, a hydraulic bag, a mechanical device having two parallel motion paddles, a mechanical device having a swivelling motion top paddle, a mechanical device having separate medial and lateral top paddles, one central arm on the femur, or only a medial separation. Each of these is configured for applying to the flexed or extended knee so that it is tensed gently but sufficiently to open the knee on the medial side to achieve the degree of tension (A-P drawer) that is closest to the normal knee. Moreover, each is configured for insertion between the tibia and femur.

The mechanical arm 34 of Dance et al. is not a tensor means (or anything equivalent) which can be applied to the flexed or extended knee between the tibia and femur. The mechanical arm 34

of Dance et al., as shown in Fig. 4 which has alignment feature 48, but it is not inserted between the tibia and the femur. Thus, Dance et al. do not disclose or suggest a tensor means as required by claim 1.

Accordingly, both Dance et al. and Brosseau et al. fail to teach or suggest a tensor means as recited in claim 1. As a result, claim 1 is submitted as patentable and nonobvious in view of the prior art including the combination of Dance et al. and Brosseau et al.

Claims 2-6 depend directly or indirectly from claim 1 and are submitted to be patentable over the references of record for the same reasons as claim 1.

B. Claims 7 and 8

To the extent claims 7 and 8 include the same recitations as claims 1 (i.e., tensor means), the claims are submitted as patentable over the references of record, including the combination of Brosseau et al. and Dance et al., in that none of them show or suggest a tensor means.

C. Claim 10

New claim 10 is directed to a system for use by a surgeon during implantation in a patient of a tibial implant and of a femoral implant in the course of a knee replacement operation. The system comprises:

- a) at least one sensor for registering the three dimensional position and orientation of a bone selected from the patient's tibia and the patient's femur;
- b) a detector for detecting the position the sensor;
- c) a computer connected to the detector, the computer being programmed to determining the three dimensional position and orientation of at least one bone selected from the patient's tibia and the patient's femur, the computer having memory for holding data relating to size and shape of at least one tibial implant and at least one femoral implant as well as data obtained

during pre-operative scanning of the patient relating to the tibia and femur of the patient;

d) a display for displaying images derived from data held in the memory of the computer; and

e) a spacer for placement between the tibia and femur and applying tension to the ligaments of the patient's knee in flexion and extension;

f) the display displaying one or more of the following images derived from data held in the memory of the computer and depicting the position and orientation of:-

(i) the patient's tibia and the patient's femur with the knee tensed by the spacer in flexion;

(ii) the patient's tibia and the patient's femur with the knee tensed by the spacer in extension;

(iii) the patient's tibia and the patient's femur with the knee tensed by the spacer in flexion and potential planes of cut for resection of the patient's femur;

(iv) the patient's tibia and the patient's femur with the knee tensed by the spacer in extension and potential planes of cut for resection of the patient's femur;

(v) the patient's tibia and the patient's femur with the knee tensed by the spacer in flexion and with at least one component selected from the tibial component and the femoral component as it will appear after implantation thereof; and

(vi) the patient's tibia and the patient's femur with the knee tensed by the spacer in extension and with at least one component selected from the tibial component and the femoral component as it will appear after implantation thereof.

New claim 10 is submitted as patentable over the references of record, including Brosseau et al. and Dance et al., in that none of them show or suggest a spacer positioned between the tibia and femur which allows extension of the patient's leg.

As mentioned before, Brosseau et al. fail to mention or suggest a spacer and therefore, is not pertinent to the

distinction that applicants submit make the present invention patentable.

Dance et al. teach a computer-assisted surgery system having a support arm 34, as shown in Figs. 4 and 5B. The mechanical arm 34 shown in Fig. 4 would not allow the knee of the patient to be extended because of alignment guide 32. As illustrated in Fig. 4, the alignment guide 32 would contact the tibia and prohibit extension of the patient's leg. Thus, the mechanical arm 34 can not apply tension to the ligaments of the patients in an extended position. Furthermore, no portion of the mechanical arm 34 shown in Fig. 5B is inserted between the tibia and femur. Thus, Dance et al. fail to mention or suggest a spacer for positioned between the tibia and femur of the patient which allows extending the patient's leg.

As a result, claim 10 is submitted as patentable and nonobvious in view of the prior art including Dance et al. and Brosseau et al.

D. Claim 11

Claim 11 includes similar recitations as claim 10, and is submitted as patentable over the references of record, including Brosseau et al. and Dance et al. The prior art of record fails to show or suggest (in the case of claim 11) "a spacer for placement between the tibia and femur for applying tension to the ligaments".

E. Claim 12

New claim 12 is directed to a method of operating a system for use by a surgeon during implantation in a patient of a tibial implant and of a femoral implant in the course of a knee replacement operation. The method comprising:

a) storing data in a computer having memory relating to size and shape of at least one tibial implant and at least one femoral implant as well as data obtained during pre-operative scanning of the patient relating to the tibia and femur of the patient and also data relating to the three dimensional position and

orientation of at least one bone selected from the patient's tibia and the patient's femur obtained during the course of the knee replacement operation;

b) registering the three dimensional position and orientation of the at least one bone during the course of the knee replacement operation;

c) detecting the position and orientation of the at least one bone and for supplying to the memory of the computer data relating to the three dimensional position and orientation of at least one bone selected from the patient's tibia and the patient's femur obtained during the course of the knee replacement operation; and

d) applying tension to the ligaments of the patient's knee in flexion and in extension;

e) displaying one or more of the following images derived from data held in the memory of the computer and depicting the position and orientation of:

(i) the patient's tibia and the patient's femur prior to resection of the femur with the knee tensed by the tensor means in flexion;

(ii) the patient's tibia and the patient's femur prior to resection of the femur with the knee tensed by the tensor means in extension;

(iii) the patient's tibia and the patient's femur prior to resection of the femur with the knee tensed by the tensor means in flexion and potential planes of cut for resection of the patient's femur;

(iv) the patient's tibia and the patient's femur prior to resection of the femur with the knee tensed by the tensor means in extension and potential planes of cut for resection of the patient's femur;

(v) the patient's tibia and the patient's femur prior to resection of the femur with the knee tensed by the tensor means in flexion and with at least one component selected from the tibial component and the femoral component as it will appear after implantation thereof; and

(vi) the patient's tibia and the patient's femur prior to resection of the femur with the knee tensed by the tensor means in extension and with at least one component selected from the tibial component and the femoral component as it will appear after implantation thereof.

New claim 12 is submitted as patentable over the references of record, including Brosseau et al. and Dance et al., in that none of them show or suggest the step of applying tension to the ligaments of the patient's knee in flexion and in extension.

Brosseau et al. teaches an interactive computer-assisted surgery system designed for use with a surgical tool which "can be, for example, an awl, a screwdriver to install, for example, an artificial ligament, or any tool used in surgical procedures" (column 4 lines 63 to 65). The method of the invention of Brosseau et al. is described at column 6 line 55 to column 7 line 30. This describes a surgical procedure for implantation of an artificial ligament in a knee to replace the anterior cruciate ligament (column 6 lines 62 to 67). The specification at line 68 states, "It is well known by surgeons specialized in knee surgery that the artificial ligament should be placed in such a way that it respects an isometry constraint." This means that the ligament must be of an appropriate length and joined to the bones in such a way that it can mimic the natural anterior cruciate ligament. Ideally it should be of the same length as the natural anterior cruciate ligament and joined to the tibia and femur at the same places as the natural anterior cruciate ligament. Brosseau et al. do not mention performance of a knee replacement operation. Moreover, the replacement of an anterior cruciate ligament does not necessitate checking the tension in the medial or lateral ligaments.

Accordingly, Brosseau et al. fail to teach or suggest the step of applying tension to the ligaments of the patient's knee in flexion and in extension as recited in claim 12.

As described above in more detail with respect to claim 1, Dance et al. teach a computer-assisted surgery system having a

support arm 34. It is stated at column 4 line 61 that the "support arm 34 is connected to registration clamp 30 and is used to rigidly position femur 10." While there is reference to arm 34 being used to move the patient's leg through full flexion to full extension, there is no reference of the arm being used for applying tension to the ligaments of the knee.

Thus, Dance et al. do not disclose or suggest the step of applying tension to the ligaments of the patient's knee in flexion and in extension as recited in claim 12.

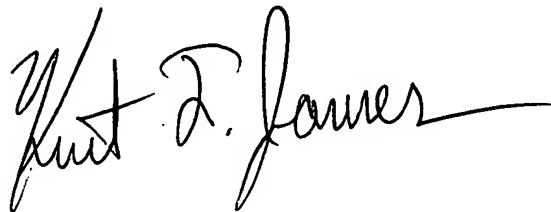
Accordingly, both Dance et al. and Brosseau et al. fail to teach or suggest the step of applying tension to the ligaments of the patient's knee in flexion and in extension. As a result, claim 12 is submitted as patentable and nonobvious in view of the prior art including the combination of Dance et al. and Brosseau et al.

Conclusion

In view of the foregoing, consideration and allowance of claims 1-12 is respectfully requested.

A check in the amount of \$647.00 is enclosed to cover the three-month extension of time fee and four additional independent claims. The Commissioner is hereby authorized to charge any fee deficiency or overpayment to Deposit Account No. 19-1345.

Respectfully submitted,

A handwritten signature in cursive script, reading "Kurt F. James", with a long horizontal flourish extending to the right.

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